**AMLUCK Enterprises Co. Ltd.**
No. 41, Ching Hsiang St., Tu-Cheng, Taipei, Taiwan, ROC 236
Telephone: 886-2-22695555 Fax: 886-2-22695115
Email: amluck@ms7.hinet.net

K012796

MAR 1 4 2002

# "510(k) Summary"

| | |
|---|---|
| Submitter's Name: | AMLUCK ENTERPRISES CO. LTD. |
| Address: | No. 41, Ching Hsiang St., Tu-Cheng, Taipei, Taiwan, ROC 236 |
| Telephone: | 886-2-22695555 |
| FAX: | 886-2-22695115 |
| Contact Person: | Mr. THOMAS CHEN |
| Date Summary Prepared: | 12/15/2001 |
| Proprietary Name: | AMLUCK BLOOD PRESSURE MONITOR AK-3000 / AK-4000 |
| Common Name: | BLOOD PRESSURE MONITOR |
| Classification Name: | NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM<br>( per 21CFR section 870.1130) |
| Device Class: | Class II (performance standards) |
| Specialty: | CARDIOVASCULAR |
| Product code: | DXN |
| Legally Marketed ( Predicate ) Device : | *MICROLIFE WRIST WATCH BLOOD PRESSURE MONITOR, MODEL BP-3BU1*<br>510(k) No: K001182 |

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## Description of the new device:

AMLUCK AK-3000 / AK-4000 uses the Oscillometric method to measure the blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to use the stethoscope, as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

## Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of AMLUCK AK-3000 / AK-4000 are substantially equivalent to MICROLIFE BP 3BU1. AMLUCK AK-3000 / AK-4000 is of generally the same form and intended to be used in the same manner as the substantially equivalent products, MICROLIFE BP 3BU1.

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## Test Summary:

1. **ELECTRIC SAFETY and EMC test reports,**

| | | |
|---|---|---|
| *General safety* | *EN 60601-1:1990+A1+A2+A11+A12+A13* | ***PASS*** |
| *EMC conformity* | *EN 60601-1-2: 1993* | ***PASS*** |

2. **WOVEN COTTON SHEETING**

   JIS L 1096 6.39.1.2 Method B 2, certified by SGS UK Ltd.

3. **PERFORMANCE & CLINICAL TEST**
   AAMI / ANSI SP10

*Amluck Enterprises Co. Ltd. believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.*

Thomas Chen

Submitter, 01/11/2002
*General Manager*
*AMLUCK ENTERPRISES CO., LTD.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 4 2002

Amluck Enterprises Co., Ltd.
c/o Dr. Yang, Tien-Hsing
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun Street
Hsin-Chu City
Taiwan, ROC

Re: K012796
Trade Name: Amluck Automatic Digital Wrist Blood Pressure Monitor AK-3000/AK-4000
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: January 11, 2002
Received: January 15, 2002

Dear Dr. Yang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

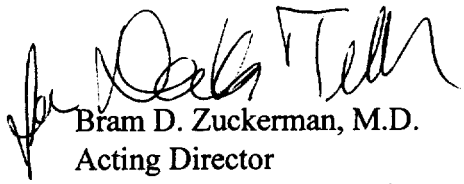
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Bram D. Zuckerman, M.D.
Acting Director
Division of Cardiovascular
And Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**AMLUCK Enterprises Co. Ltd.**
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Telephone: 886-2-22695555 Fax: 886-2-22695115
Email: amluck@ms7.hinet.net

Applicant: AMLUCK ENTERPRISES CO., LTD.

510(k) Number ( if known): TBA K012796

Device Name: AMLUCK AUTOMATIC DIGITAL WRIST BLOOD PRESSURE MONITOR AK-3000 / AK-4000

- *Indications for use:*

The Amluck automatic digital wrist blood pressure monitor, Model AK-3000 / AK-4000, is a noninvasive blood pressure measurement system intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. The cuff circumference is limited to be 5.3" – 8.5".

( PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE )

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Concurrence of CDRH, office of Device Evaluation (ODE )

Division of Cardiovascular & Respiratory Devices
510(k) Number K012796

Prescription Use _____ OR Over—The—Counter—Use ✓

( Per 21 CFR 801.109 ) ( Optional Format 1-2-96 )